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Fish & Richardson  
4350 La Jolla Village Drive Suite 500  
San Diego, CA 92122

EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/807,123

Applicant(s)

DOI ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

Claims 1-12 are at issue and are present for examination.

### ***Information Disclosure Statement***

Applicants filing of information disclosure, Paper No. 5, filed 4/5/2001, is acknowledged. Those references considered have been initialed.

### ***Specification***

The disclosure is objected to because of the following informalities:

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s): 37 CFR 1.821. (d) states "Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing " in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

The sequence listing of the instant application lists 11 separate sequences, and while these sequences appear throughout the specification, there is no reference made to SEQ ID NO: 9-11 by sequence identifier as per 37 CFR 1.821. (d). Applicant is

referred to Section 2422 of the M.P.E.P., Nucleotide and/or Amino Acid Sequence  
Disclosures in Patent Applications.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 4 and 6 are indefinite in that they each depend from claim 1, and each claim attempts to further limit claim 1 by limiting the polyester polymerase protein (claim 2),  $\beta$ -ketothiolase protein (claim 4) or NADPH-acetoacetyl CoA reductase protein (claim 8) to a specific sequence (i.e. SEQ ID NO: 2, 4, 6 or 8). By virtue of part (b) of each of these claims which recites "a protein having an amino acid sequence including deletion, substitution, or addition of one or more amino acids relative to the amino acid sequence represented by SEQ ID NO:...", each of the claims do not further limit claim 1 and are therefore identical to claim 1.

Claims 3, 5 and 7 are indefinite in the recitation of "stringent conditions" as the specification does not define what conditions constitute "stringent". While page 7 of the specification describes some conditions which are "included" in stringent, there is

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nothing to suggest that other conditions would not also be included within the scope of this term and in the art what is considered stringent varies widely depending on the individual situation as well as the person making the determination. As such it is unclear how homologous to the sequence of a DNA containing SEQ ID NOs:1, 3, 5, or 7, a sequence must be to be included within the scope of these claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 6, 8 and 10-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 2, 4, 6, 8 and 10-12 are directed to all possible transformants obtainable by transforming any host, whose polyhydroxybutanoic acid polymerase gene is disrupted, with a recombinant vector containing any polyester polymerase gene, any  $\beta$ -ketothiolase gene and any NADPH-acetoacetyl CoA reductase gene (claims 1, 2, 4 and 6), wherein said transformant is a bacterium belonging to the genus *Pseudomonas* or the genus *Ralstonia* (claim 8) and methods of producing a copolymer comprising culturing said transformants (claims 10-12). The specification, however, only provides a single representative species of transformant, *Pseudomonas* sp. strain 61-3 (JCM10015) transformed with a recombinant vector comprising the DNA sequences of

SEQ ID NOs : 1 or 3, 5, and 7, encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these transformants and the DNAs by any identifying structural characteristics or properties. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

Claim 9 and 10-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention of claim 9 appears to employ a novel strain bacterium, *Pseudomonas* sp. strain 61-3 (JCM10015). Since bacterium is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The organism is not fully disclosed, nor has it been shown to be publicly known and freely available. The enablement requirements

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of 35 U.S.C. § 112 may be satisfied by a deposit of the *Pseudomonas* sp. strain 61-3 (JCM10015).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-8 and 10-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Matsusaki et al. (Applied Microbiology and Biotechnology, Vol. 53, pages 401-409, 2000, See IDS).

Matsusaki et al. teach *P. putida* and *R. eutropha* PHA-negative mutant transformants in which each of the transformants is transformed with a recombinant vector containing a  $\beta$ -ketothiolase gene, a NADPH-dependent acetoacetyl-CoA reductase gene and a polyhydroxyalkanoate synthase gene.

### ***Of Interest***

While Matsusaki et al. (Journal of Bacteriology Vol 180, No. 24 December 1998, pages 6459-6467) teach the cloning and creation of recombinant vectors comprising the polyester polymerase,  $\beta$ -ketothiolase and NADPH-acetoacetyl CoA reductase genes of *Pseudomonas* sp. Strain 61-3, as well as the creation of a polyhydroxybutanoic acid

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polymerase gene (*phbC<sub>PS</sub>*) negative mutant of *Pseudomonas* sp. Strain 61-3, they do not teach or offer motivation to transform such a negative mutant with a recombinant vector comprising the genes encoding polyester polymerase,  $\beta$ -ketothiolase and NADPH-acetoacetyl CoA reductase.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



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A handwritten signature in black ink, appearing to read "Richard Hutson", with a long horizontal stroke extending to the right.

Richard Hutson, Ph.D.

Patent Examiner

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January 24, 2003